UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

- - -

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION : MDL NO. 1968

(This document relates to all cases.)

- - -

CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

Wayne, New Jersey
Monday, January 18, 2010

- - -

Videotaped Deposition of PHYLLIS A. LAMBRIDIS, held at Ramada Inn, 334 US Rt. 46, on the above date, beginning at 9:06 a.m., before Kimberly A. Overwise, a Certified Realtime Reporter and Notary Public.

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EXHIBIT B

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Golkow Technologies, Inc.

Mike Kauffmann

"Recalls have not been issued."

Do you know what that relates to?

A As I look at this, it looks like it's a recap of some of the concerns expressed over the course of the investigation. So it doesn't necessarily reflect the state of affairs at that point in time.

Q Okay. So the bullet point that says "Recalls have not been issued," are you saying that that doesn't really reflect the state of affairs as of May 20th?

A Correct.

Q Okay. The next bullet says: "Health hazards related to recalls are delinquent."

What does that mean?

A When you -- when there's a recall or you're considering a recall or you are -- you have a product that may be -- may potentially be a recall, the company typically would look for expert opinion, which they call a health hazard assessment, as to the nature of what the severity of the issue might be. And in some cases, the health hazard assessment

will -- might even tell you that there is no issue. And it helps you to justify to FDA why you may not do a recall.

In this particular case, we also -- companies would also do this because FDA is the final -- makes the final determination on the level of a recall, but a company would typically do their own health hazard assessment to try to work with FDA to minimize the impact of what level of -- you know, to determine what level, to talk with them and get their own personal assessment.

So in this particular case, we had done health hazard assessments on several of the products that were the subject of recalls that were in process; and they weren't satisfied with all of the content, or some of them were not timely.

Q Okay. So do you know whether one was done for Digitek?

A I honestly don't recall.

Q Do you know who did the health hazard analysis for Digitek if it was done?

A If it was done, it would have been

Q Yes.
A I don't recall.
Q Then the next bullet says: "That you put effective Quality Systems in place."
Do you see that?
A Yes.
Q And do you agree that as of May of 2008, there weren't effective quality systems in place for Actavis Totowa?
MR. DEAN: Object to the form.
Go ahead.
THE WITNESS: That was Erin's statement.
BY MR. BLIZZARD:
Q Okay. Did you agree with FDA on that issue?
A Not necessarily, no.
Q Did you agree with it at all?
A I agreed that that was her view and, based on what she had seen, that she had come to that conclusion.
Q And she was acting on behalf of FDA in coming to that conclusion; correct?
A Yes.

Q Do you see the next bullet says: "Get very nervous when you tell us that you are releasing product using the current Quality Systems (open issues remain)."

Do you see that?

A Yes.

Q Were you nervous -- well, let me stop you there.

Was there product still being released by the Little Falls plant at this period of time?

A As you pointed out earlier, the PAREXEL consultants were engaged the end of April. And at that point in time, we stopped shipping product, end of April. But after PAREXEL came in, they were reviewing product by product. And some additional products started to be released again based on the PAREXEL review.

Q And this -- sorry. Go ahead.

A I believe her statement here, she was referring to herself --

Q Right.

A -- that she gets nervous that we are

still releasing product.

Q And she's charged with making sure that US citizens receive safe drugs; correct?

MR. DEAN: Objection; calls for a legal conclusion.

Go ahead.

THE WITNESS: She's part of the organization that does that.

BY MR. BLIZZARD:

Q Right.

A As a consumer safety officer, yes, that's her job.

Q And then the next one, bullet point says: "Do not fix broken Systems - get new Systems. (I can't tell you what to do but start from scratch)."

Do you see that?

A Yes.

Q So you agreed with her that the system was broken and needed to be fixed?

A That's a very general statement. I think there were definitely systems that required some improvement. And there were still systems, I think, in place that were

working. So I would have to say I would agree perhaps on some of the issues and disagree on others. It would have to be more specific.

Q Which parts of the quality system, both quality assurance and quality control, did you think were broken and needed to be fixed?

A There were SOPs, I believe, that needed to be perhaps put into more detail regarding investigations and other things that she had noted that were obviously not the ones that weren't closed, et cetera, and some other areas.

I would have to go back and really look, but not -- when you referred to systems, FDA's view is there's six systems; and she's, I think, here not referring to the whole entire company. She's referring to the systems that she's looked at.

Q Right. And she's saying that they're broken and need to be fixed and you should start from scratch; right?

A That's her opinion, yes.

Q Right. And essentially did the

Q And were there any other Patels that were involved -- any family members of the Patel family who stayed on after the acquisition of Amide Pharmaceuticals and worked for Actavis?

A I cannot recall her first name in both cases. There was a sister with a different last name -- she had a married name. I can't remember what it was -- employed in the legal department. And his mom, I think it was Nila Patel. I'm not sure. She was employed at the Little Falls facility in more of an office manager's role.

Q Now, following the FDA inspection and through the time that you worked at the company, did any of these, the Patel family members, stay on with the company?

A Up until I left, I believe the only person that was still employed was the sister.

Q That was in the legal department?

A Correct.

Q Okay. Now, back at the time that this inspection was going on in April of 2007, did you communicate with Divya Patel about

what products should be fixed in what order?
A We talked about what products needed to be addressed in terms of reintroduction because we were discontinuing product as a result of some of the activities.
We had some discussion about the recalled products and what needed to be done to enable us to market them. Again, that was the initial part of that discussion.
Q And was Digitek among the recalled products?
A Yes. Well, the first recall didn't involve -- the first group of products that were recalled, Digitek was not -- Digitek stood alone. It was handled in a different manner because we did not market that product. It was marketed by another company.
Q Okay. And that other company was Mylan?
A Correct.
Q So the recall that was done for Digitek was handled separately because of Mylan's involvement; correct?
A And because we had already committed

A Can you say that again, just repeat it?

Q Let me ask a different question.

Do you see where it says "For the products that we want to stop and fix" -- do you see that?

A Yes.

Q -- "can you give me a first pass on the order of priority that you would like them assessed."

So were you asking these management people to give you some idea of the priority order for reassessing these products that you were going to stop and fix?

A Yes. I can explain if I can just put it into context.

Q Sure.

A At this point in time, there were, as I had mentioned before, a group of products that we were recalling. There were several things going on. If you refer back to this memo --

MR. DEAN: "This" being 107?

THE WITNESS: -- 107 exhibit,

we made some commitments to FDA to recall product. And that was outlined in a memo that was given to the Agency.

In addition to that, we agreed -- because those recalls were full recalls, so they involved taking all of the product for those products off of the market, they were affectionately known as the stop-and-fix products.

So the plan at the time was to -- at least we had stopped obviously manufacturing and shipping them. And the plan at the time was to evaluate them to determine whether they would be reintroduced and what would be needed before they could be reintroduced.

And the reason for that is because in some cases there were method-related issues or issues that could improve the product that may -- would require a lot of resources or FDA review that would be a lengthy review. So it was a business decision as to whether they were worth spending the time

as opposed to spending that time and resource elsewhere.

So that's the context of what's there. So one of the things that we presented to FDA, again back to the Exhibit 107, on April 9th, the memo that's referred to here, this FDA memo, we committed to recalls of those products; but we also were doing this rationalization.

So that list consisted of the products, these stop-and-fix products, and then other products that we were, for business reasons, most likely going to discontinue, and then the products that would remain.

BY MR. BLIZZARD:

Q Okay. I think I understand. So what you're saying is there were these products that the company was -- we're calling stop-and-fix products, and digoxin was not a stop-and-fix product?

A No.

Q But if you look at Exhibit -- if we

mentioned earlier, was a new building that we were planning to move into.

So the context of that inspection was to come in and give a preapproval of that facility so that we could move into it. So that's the preapproval part of it. And as part of any preapproval inspection, they also do a GMP inspection.

Q Okay. So what this was originally -- was this originally a preapproval inspection, but it turned into a GMP inspection?

A It was originally a preapproval inspection which would have included GMP, but we -- she started doing the GMP portion of it, and we never got to the preapproval portion of it.

Q If you look over on the next page, Page 2, you see where it says beginning on the -- I guess it's the first full sentence on that page, "The previous inspection"?

Do you see that sentence?

A Yes.

Q The previous inspection of the

Little Falls, New Jersey, facility provided coverage of the quality, production, laboratory control, materials and facilities and equipment systems. Deficiencies were documented in the areas of field alerts, the stability testing program, and investigations.

And then the last sentence says: Corrections were promised for all observations. The inspection was classified as -- is that a VAI?

A Yes.

Q What is VAI?

A Voluntary action indicated.

Q So that refers to a previous inspection of the same facility; is that true?

A Actually, it's an inspection of the Little Falls facility on Main Street, not the Riverview facility, but it's all Actavis Totowa.

Q Okay. So it was an inspection of the Little Falls plant?

A Yes.

Q Were you involved at all in that inspection?

A That inspection took place just prior to my arrival, so it was in process when I started with Actavis. And my only involvement was to attend again the closeout meeting that they held at the completion of that inspection.

Q Did you actually -- were you provided with any of the 483 materials so that you could be familiar with the issues at the plant going forward?

A Yes.

Q So you were familiar with what findings had been made in 2006 regarding the Little Falls facility in the 483 inspection?

A No. This was 2007. This inspection that I'm referring to was September of 2007.

Q Okay. So did you know about an inspection in 2006 of the Little Falls facility?

A Yes.

Q And when did you learn about that?

A Actually, I was aware of it prior to joining the company.

Q How so?

A Because they had been issued a warning letter, and just normal surveillance as part of my job. I know -- I keep up on what's going on with other companies, and it's in the news --

Q So was it --

A Trade press.

Q I'm sorry.

A Sorry. That's okay.

Q So that was part of your role as a consultant or while you were working for another company?

A No. It was just knowledge I had prior to joining.

Q Okay. So you saw the warning letter that was issued in 2006 to Actavis regarding the Little Falls facility?

A Yes.

Q And that was as an industry observer, I guess?

A Correct.

Q Did you do any further research on that subject when you arrived at the company?

A No.

A Correct.
Q And then if you go down to the middle paragraph that starts on April 9th, do you see that?
A Yes.
Q On April 9th, a written commitment was provided by yourself, and it shows it's Exhibit 12. And it says in the middle of the paragraph: "The letter also included a plan to stop and remediate numerous products/processes due to the current cGMP findings."
Correct?
A Yes.
Q Is that the stop-and-fix list that you talked about earlier?
A Yes.
Q And then it says at the last sentence: The District was formally notified of a probable Class I recall of digoxin tablets, .125 milligrams, and then it gives the lot number; correct?
A Correct.
Q Okay. Now, if you go over to

discuss the upcoming exit meeting; correct?

A Correct.

Q And then if you look at the top of the next page, does it say there: "Both Ms. Eyjolfsdottir and Ms. Lambridis acknowledged the severity of the cGMP deficiencies and stated the need for corrective actions, restructuring of the Quality Unit, and hiring"?

Do you see that?

A Yes.

Q And do you recall making that admission?

A Yes.

Q And it was accurate and correct?

A Based on what was presented to us, yes.

Q Right. And part of this, these deficiencies involved the drug Digitek; correct?

A Yes.

Q Now, if you'll go over to Page -- I'm going to skip a few pages now -- Page 15, do you see there's a paragraph there that

[redacted]

Q Okay. Did you subsequently have any conversations with Mr. Wessman or Mr. Olafsson about the commitment to not produce any more digoxin until there was tableting equipment with weight controls?

A I was present during some of the discussions with senior management regarding Digitek. And the context of this was that they would not produce -- if they were going to move forward with digoxin, that they would want to purchase equipment with weight controls.

Q Okay. And I take it that there wasn't any existing equipment at the Little Falls or Riverview plant that was a press with weight controls; is that true?

A I'm not sure if there were none, but the presses -- majority of the presses there were not automated. So there might have been one. I'm not sure.

Q But there wasn't enough presses that were automated to produce digoxin with presses that were all weight controlled; is that true?

[redacted]

Q It says here that Chuck Koon and Becky Pinnell had an informal conversation with Dan Bitler, Actavis quality, regarding the ongoing FDA inspection of the Little Falls facility. And he's providing a brief summary below; correct?

A Yes.

[redacted]

Q It says: The company has halted production of all products at the Totowa Little Falls, New Jersey, site.

Is that accurate?

A Yes.

[redacted]

Q Did any -- was there any attempt that you're aware of to buy a new press with appropriate weight control during the time that you remained employed by Actavis?

A Not for Digitek.

Q Okay. Were there other automated presses bought with weight controls that were used to manufacture drugs other than Digitek after the FDA inspection?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: I can answer?

MR. DEAN: You can answer, sure.

THE WITNESS: We did evaluate that. I don't recall what was purchased or if anything was purchased.

BY MR. BLIZZARD:

Q Okay. So you don't know one way or the other?

A No.

Q In August of 2008, you were still employed with the company?

A In August, yes.

Q And there were -- the remediation effort or the effort on the corrective action plan, was it still underway at that time?
A Yes.
Q And had some of the items on the corrective action plan actually been completed?
A Yes.
Q Were there others that were incomplete in August of 2008?
A Yes.
Q Were there still significant weaknesses within the quality department and the quality system as of August of 2008?
A We were still in the process of putting together a robust quality system to inspect -- that would hold up to inspection. So I think that there was still a lot of work that needed to be done along those lines. I don't know that I can say there were weaknesses.

(Plaintiff's Exhibit No. 116 was marked for identification.)

That's a miscategorization of that sentence.

BY MR. BLIZZARD:

Q Does the sentence say: They -- "The quotes they lifted are in every warning letter and recall press release"?

A Yes.

Q And in the second paragraph, is there a quote there that says: Actavis said August 1 that it is recalling all 65 products manufactured at the plant following an inspection that, quote, revealed operations which did not meet the FDA's or Actavis' standards for good manufacturing processes?

Did I read that correctly?

A Yes.

Q And do you agree that the inspection by FDA did reveal operations which did not meet the FDA or Actavis' standards for good manufacturing practices?

A Yes. But that is also a standard statement that is in most recall notices.

Q Well, is that something that you think the public should be entitled to know?

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Do you see the first e-mail here is from Tony Delicato to Erislandy Dorado with a carbon copy to you and Chris Young?

A Yes.

Q And it's dated September 16 of 2008; is that right?

A Yes.

Q And then the subject says: "These are just examples - not all - inclusive."

Is that what it says?

A Yes.

Q And it says: Quality unit responsibilities SOP outdated/not accurate.

Do you know what that refers to?

A There was an SOP, a standard operating procedure. And the one that was in place did not reflect what was -- what we wanted to have going forward, so it needed to be revised.

Q Then it says: Quality review board - SOP effective but no meetings held as functional areas have not had time to generate metrics.

professionals in multiple industries, not just in pharmaceuticals.

Q There is the phrase "visual inspection" in some of these documents, "AQL," and "tightened AQL." For this particular investigation, 07-093, of this particular batch, can you tell me, was there a visual inspection, was there an AQL, and was there a tightened AQL? Were there all three?

A There was a visual inspection and a tightened AQL. There's typically a normal AQL for the release. But that was -- I don't -- I didn't review that, so I can't say for sure.

But that would typically happen at some point during the manufacture of the batch in order to get that batch through to the point where it would be packaged and released. So it may be in the regular batch documentation, which I don't have in front of me.

Q So now I'm not talking about this particular investigation, but there could be such a thing as a visual inspection and then an AQL and then a tightened AQL? Is that

possible, generally speaking?

MR. DEAN: On one batch; right?

MR. PETTIT: On one batch, yes.

THE WITNESS: Under normal circumstances, there's an AQL and the batch is released. Because this batch identified a problem -- in any batch that identifies a problem, it is possible that they would do a visual inspection and then another AQL before they release it.

BY MR. PETTIT:

Q So it is possible that you could have a visual and an AQL and a tightened AQL; that's possible?

A Yes, but not in that order.

Q What would the order be?

A It would be AQL, visual inspection, tightened AQL.

Q And the decision to have a tightened AQL would be made by whom, generally, at Actavis in 2007?

A It would typically be done by -- at Actavis it would be done by the director of QA, but it's standard practice. It should be

that there was a total failure of the quality department at Actavis during the inspection of 2008?

A It's a little out of context, but I believe the discussion was whether or not I agreed to it in a conversation with Erin during the closeout -- or during a meeting with Erin.

Q Did you, as the vice president of quality and compliance, during the FDA 483 in 2008 believe that there was a total failure of the quality control system at Actavis? And when I say that, I mean Little Falls and Totowa.

A We didn't present ourselves well to FDA, for sure. So it was very hard for me to disagree with Erin during our discussions because based on what she had reviewed, there were numerous issues that she was able to raise that, again, needed attention.

So, again, based on -- in the context of what we were talking about and based on the issues she presented, it was not -- it was something that I couldn't

refute.

Q Do you believe, as you sit here today, that if all the findings were presented in a different manner, that the production of 64 products would not have been discontinued?

A I don't understand the question.

Q Are you telling me that it was the way that the violations were presented or the inspection was presented that would have classified it as a total failure of QC?

A No. What I'm saying is that she reviewed a group of products that were known -- already known issues that -- and the reason that she focused on those is because we had already informed the Agency that we had a problem.

So when you're only looking at a problem, your conclusion -- her conclusion was then broadened to include everything. And her comments were based on a sampling of the many products that Actavis was making at the time.

Q So it's your belief that because she found issues with certain products, that it didn't carry over to other products?

A Say that again.
Q Well, you were indicating that Actavis stated that there were problems with certain products, and those were the products that they investigated?
A There's a mechanism and a requirement that if you have an issue -- if you do an investigation on a product that's been marketed, that you have an obligation to notify FDA.
So there were a number of -- and even without that, every FDA inspection, when they look at the quality system, it typically asks you for documents related to your investigations, your complaints, and so forth. And they use that as a gauge for what they're going to look at. So they come in, and she was looking at our investigation log and looking at investigations specifically. So obviously she was going to be looking at problem areas.
Q But you agree with me that it wasn't so much the investigation that led to the violations of GMP but how the investigations

were handled?

A Correct. She was not happy with how certain ones were handled. And how we got to it broadening beyond that was the fact that she focused on a certain number of products and then drew her conclusions based on that.

Q At the time of the inspection, Actavis was manufacturing 64 products; is that correct?

A I don't recall the number, but there was at least that.

Q Okay. And at least that and my list is including the Digitek. And my question is: You agree that 64 products, including Digitek, were discontinued because the quality control system at Actavis had several failures?

A I'm trying to find a short way to answer that. One thing led to another is the easiest way for me to say that. We talked earlier about PAREXEL's review and discussions that occurred with the Agency even prior to the inspection closing.

So Erin looked at a number of products that were subject to investigations

and was drawing conclusions and was asking us to prove to her that that wasn't the case with all products.

So that was why we had engaged PAREXEL. That was to get a third-party, unbiased review of these other products so that we could provide that evidence to the Agency to show them that the issue was not widespread.

Q But ultimately the FDA concluded that the issue was widespread?

A Based on Erin's comments, yes.

Q Based on the FDA inspector's comments?

A Right.

Q And did you find any fault with the FDA inspector's comments?

A I -- there were things that we did disagree on. But her comments were basically accurate, you know -- yes, her comments were accurate. What she presented was accurate.

Q As you sit here now, anything -- do you recall anything specifically that you disagreed with the FDA inspector as far as her

findings during the 483?

A Fundamental issues. I mean, Erin is a very good investigator, very thorough, but she has her own opinions, like anybody does. So she had feelings about things that we implemented that perhaps were given the go-ahead by prior FDA investigators that perhaps she felt differently about.

So there were things that were discussed during the course of the investigation that I viewed one way and she viewed another, but that's not unusual.

Q Can you think of any specifics, any issues or topics that she viewed one way and you viewed another?

MR. DEAN: I've been letting -- let me just object. I'll try to be succinct here. I've been letting the general inquiry about non-Digitek products go at a general level.

I don't object to her answering that question as to Digitek specifics. But as to general details -- I'm sorry -- as to specific details of discussions she

had with Erin about non-Digitek products, I'm going to instruct her not to answer the question as to details.

I might at a general level if you're inquiring about whether there was a concern about quality control; but as to the specifics, I'm going to instruct her not to answer on non-Digitek products.

BY MR. MILLER:

Q Were there any specifics that you recall that you disagreed on from the findings of the FDA inspector during the '08 483 inspection?

MR. DEAN: Let me just instruct you just to answer that with respect to Digitek.

BY MR. MILLER:

Q And I'll point out that you can answer with respect to Digitek or any general GMP violations. It can be general issues or Digitek. It doesn't have to be just Digitek.

MR. DEAN: At a general level, I'm fine. But if you're asking her for

specific comments about non-Digitek drugs, I think that is beyond the scope of what's in PTO-12 and 27. If you're at a general level, I'm okay with it. But I think your last question could lead her to go into specifics. And I'm just instructing her, as to specifics, to limit it to Digitek.

BY MR. MILLER:

Q If you understood all those instructions, ma'am, it's okay to answer.

A I think I can answer it. In the case of Digitek and with some of the other drugs that were recalled, I didn't always see the logic in extending it to all batches. And that doesn't mean that I didn't execute on all batches because there was -- when you're dealing in a situation as I was in, you get to a point where you just -- in order to advance to the next point and not belabor the point, there's certain concessions that are made.

So in the case of some of the other recalls, which based on his instruction, I'm not going to give you the detail, but there

were situations where there was an issue with one batch and, through her interpretation, it implicated all batches.

Q How many -- I'm sorry.

A And I didn't always agree with that.

Q How many of the 64 products, give or take -- I understand your position there -- were ultimately recalled?

A All the products were recalled.

Q And was that every batch in every product?

A Yes.

Q So --

A But there were multiple recalls, so you have to distinguish one from the other. There was a set of recalls that was done initially for stability-related issues. Those are the ones that I'm referring to now when I say that one batch with a problem, even though it was a stability batch, to me did not always mean or based on -- based on the issue -- again, I can't go into detail.

But her view was that it should have been all batches based on that, and my view

was that I didn't believe that was the case. But I didn't argue that point. I conceded that point, and we recalled everything.

The 65 products that you're referring to is part of the last recall. And that recall, again, was a concession to remove product from the market in order for Actavis to even have a discussion with the Agency about next steps and getting their site back into a position where they can manufacture product.

Q Okay. Sixty-five products was the last set?

A Was the last set.

Q How large were the other sets? I thought 65 was the total universe of products at Actavis, Little Falls, Totowa?

A I don't recall, but I don't think so. I think 65 was the last set.

Q And, in your mind, Digitek was one product that was recalled on its own set?

A Correct.

Q Okay. And then there was a -- was the stability recall, was that the group of 65

or was that a subset of the 65?

A The stability group was the first set of recalls around the same time frame as the digoxin recall. And I don't recall if -- I think it was about a dozen products.

Q Was there also an out-of-specification group, an OOS group?

A That's the stability group.

Q That's the stability. Okay. Am I correct in saying that if a manufacturing company of pharmaceutical products violates a CGMP, that it's viewed that the lab has violated that CGMP for all products?

MR. DEAN: Objection to form.

Go ahead.

THE WITNESS: I don't understand the question.

BY MR. MILLER:

Q Have you seen -- I'm going to hand you what's been previously marked, if you bring up, Mike, a copy of Exhibit 82, which was the Complaint for permanent injunction.

Have you seen this document before?

A Yes.

Q And what was the occasion which you had an opportunity to read it?

MR. DEAN: Let me just instruct the witness she can answer questions at a general level about this document; but, again, given PTO 12 and 27, I don't want her to get into specific discussions of products other than Digitek. But she can answer your questions at a general level regarding this document.

Go ahead.

BY MR. MILLER:

Q Well, this document was filed, if you look at the last page, on November 14th, 2008. And you were in your position as vice president of quality and compliance at Actavis at that time; correct?

A No. I resigned on the 13th. This document was filed but not in this form.

This is the final consent decree? Is that what I'm looking at?

Q No, ma'am. This is the Complaint that led to the consent decree.

A Oh, this is the Complaint.

manufactured at this time would be considered adulterated drugs?

MR. DEAN: Objection to form. Excuse me. What drugs are you asking about? I want to be more specific.

MR. MILLER: Drugs manufactured by Actavis at Little Falls and Totowa.

MR. DEAN: And your question is what?

BY MR. MILLER:

Q Would you have considered -- did you, as the vice president of quality and compliance, agree with the Department of Justice that the drugs manufactured were adulterated drugs?

MR. DEAN: Objection; calls for a legal conclusion.

Go ahead.

Go ahead.

THE WITNESS: Answer it?

I wouldn't agree that -- no, I don't agree with the Department of Justice. I believe that there were issues involved with certain batches with

certain products that may have violated GMP and may have had issues, but I don't agree that all the drugs manufactured.

BY MR. MILLER:

Q Were GMPs violated in the production of Digitek?

A Technically, no. They followed standard practices. They did an investigation. They did all the necessary things that they should have done.

I think it was a judgment call perhaps on the amount of scrutiny that they put that batch through after finding such an issue. And it's always easy to look at it in hindsight and think of 50 other things you should have done.

But there was nothing related to that -- the only thing that I can -- they followed procedures that were in place. There was a mechanism in place. It was not done randomly.

Q I understand your answer to go specifically to the double-thick pills.

A Correct.

Q And I'm more of a broader question. The production of Digitek, if one were to review the 483 and all the write-ups, you agree that there were other write-ups about digoxin and Digitek other than the double-thick pills?

A I don't recall. I thought the majority of what was there was related to the one batch, but I don't know. Without seeing that, I couldn't comment.

Q All right. We'll certainly cover that as well.

Mike, would you blow up Paragraph 12, please.

FDA's inspections establish that the drugs being manufactured and distributed by Defendants are adulterated within the meaning of 21 USC 351, Paragraph (a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the GMP requirements for drugs.

So --

MR. DEAN: Let me just -- is that just -- you're reading the question, and you're going to ask if you read it right? Or do you have a question?

MR. MILLER: You cut me off before I even got a chance to ask a question, Dick.

MR. DEAN: Go ahead and ask your question.

BY MR. MILLER:

Q Did I read that correctly?

A Yes.

Q And it's your testimony here that you disagree with that, or do you agree with that paragraph?

MR. DEAN: Let me object and reiterate the objection I gave before and instruct her not to answer about details of other non-Digitek drugs. She can certainly answer about Digitek, and she can answer at a general level.

Go ahead.

THE WITNESS: To me, this

paragraph just states what FDA does. FDA inspections establish that. It doesn't speak specific to Actavis. It's just stating that.

BY MR. MILLER:

Q Well, you're not an attorney; correct?

A I'm not an attorney.

Q If you go to that first page, ma'am, this is a Complaint that the United States of America filed against Actavis Totowa and other defendants.

And enumerated Paragraph 12 is: "FDA's inspections establish that the drugs being manufactured and distributed by Defendants are adulterated."

It's not what the -- I'll represent to you that it's not what the FDA does. It's not explaining a duty. It's explaining a finding that if methods used or facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the CGMP requirements for

drugs, what they've done is defined what an adulterated drug is.

Do you understand the paragraph, ma'am?

MR. DEAN: Same objection. She can answer with regard to Digitek.

I instruct you not to answer as to the specifics on other drugs.

Go ahead.

THE WITNESS: I'm sorry. Now that I'm rereading the paragraph, can you ask me the question again?

BY MR. MILLER:

Q Certainly. Do you feel that you understand the paragraph now?

A Now I understand the paragraph, yes.

Q Had you received training in CGMPs as a vice president of quality and compliance?

A Yes.

Q Are you familiar with US -- with 21 USC 351 (a)(2)(B)?

A Actually, not specifically. I couldn't tell you what that reference is in detail. GMPs are Sections 210 and 211 cited

use to manufacture is how you manufacture that drug.

And there's a formulation that's associated with a certain drug. And not all drugs are produced with the same formulation or the same process.

BY MR. MILLER:

Q You would disagree with the statement that if a quality control system department of a pharmaceutical lab had a GMP violation in stability, that that general GMP violation doesn't carry over to stability for all products?

A Still, it's not -- it would depend on the case. You're -- you can have a stability issue or a problem with -- it would vary -- you'd have to be more detailed to that.

Q As we sit here, you're not aware of any GMP violations on Digitek in particular?

A No, I'm not aware of any on Digitek in particular.

Q Let's go to Page 7 of the Complaint, Paragraph 16.

Blow that up, please.

Paragraph 16 states that the FDA's inspection of Actavis Totowa's Little Falls facility from January 10 to February 8, 2006, revealed that the firm failed to comply with GMP requirements in several respects, including, for example, it failed to investigate unexplained out-of-specification testing results for drugs, specifically 21 CFR 211.192.

And my question is: Do you agree that failing to investigate unexplained out-of-specification testing is a violation of CGMP?

MR. DEAN: Objection; calls for a legal conclusion.

Go ahead.

THE WITNESS: Yes, it is a violation.

BY MR. MILLER:

Q If we go to Page 10 and take a look at Paragraph 21, the Complaint by the US Department of Justice goes on to say that from March 18 to May 20th, 2008, FDA inspected

Actavis Totowa's Riverview Drive facility. Throughout the inspection, the FDA investigators advised defendants of the numerous and significant deviations from the CGMP requirements that the investigators observed so the firm could take responsive actions to protect the public health.

Ma'am, you would agree that you were part of the conversations in which the FDA investigators advised Actavis of the numerous and significant deviations from CGMP?

A Yes.

Q And do you agree that there were numerous and significant deviations from CGMP during the March 18th to May 20, 2008, inspection?

A Yes, I would have to agree.

MR. MILLER: Would you call up Exhibit 91.

BY MR. MILLER:

Q That first page -- we've gone over this document in some detail. I'm going to make a very good attempt not to ask questions that have already been asked, although I'm

GMP inspection," would they look at good manufacturing practices -- if they look at, say, stability and the amount of time that you have in this field, will they go through and qualify GMP stability for every product or do they qualify stability for one or two products? They wouldn't go through 64 products? -- is my question.

A Correct.

Q So there's a general term there where, okay, three or four products or whatever number it might be are approved for GMP for stability, or any other example, then it's approved across the board; is that correct?

A They look at the system itself, and they use a sampling of the products to determine if that system's working.

Q Would you agree with me that when they look at the system, again, they look at stability; they don't look at stability for each and every of the 64 products; is that correct?

A Correct.

Q And does the counterpart hold true? When they come in to inspect, they won't inspect every product's stability testing; they'll inspect a couple and then say you violated the GMP for stability across the board; is that correct?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: If it's not specific to a product, yes, then that would be true. So if they found a problem that was related specifically to one product, then you couldn't make that assumption. But if they found a general problem, then you could.

BY MR. MILLER:

Q Would you describe a general problem? If they found GMP violations in three or four products out of 64, that then does it become a general problem?

MR. DEAN: Objection; incomplete hypothetical.

BY MR. MILLER:

Q It's okay to answer.

before it is an across-the-board, general problem?

MR. DEAN: Objection to form; vague, ambiguous; lab system's undefined, numerous other terms undefined. The question is vague and ambiguous.

BY MR. MILLER:

Q It's okay to answer.

MR. DEAN: Go ahead if you can.

THE WITNESS: I forgot the question.

BY MR. MILLER:

Q Using your term, "laboratory system," stability testing falls under laboratory systems, which we have established. And you indicated that one would be a problem with that product, and you also indicated that "multiple" would be an indication of across-the-board problem.

My question is: How many?

A How many? There's no definitive number.

And just to clarify, in this particular case, we had multiple stability

failures that led to recalls and those products were recalled; but they were product-related because, generally speaking, the lab got a clean bill of health in this inspection, for the most part. That was the area that they praised in terms of labs. So the fact that the lab found the out-of-specs, I mean, it went to their credit.

If you recall, you put something up a few minutes ago that criticized the company from the prior inspection, whereby they were not opening any investigations. And you asked me if that was a violation of GMP, and it is.

So the company had come quite a ways in that they were opening these investigations. Now, of course, they were now cited for failing to close them in a timely fashion, but it was a new problem. It was a related problem.

But now the company was -- the laboratory was actually given kudos for the fact that it had done well during this inspection, despite the stability failures because they were product-related. They were

related to either an issue with a product or a batch or a method or something, something else.

MR. MILLER: Let's go to Page 2 of 95. And blow up the last five lines. There's a sentence that begins with "however."

BY MR. MILLER:

Q And if you could start, read whatever you need to catch up. But it begins with "However," the bottom of the page, four or five lines up from the bottom.

And it says regarding this inspection: However, there is no assurance of the strength, quality and purity of the approximately -- redacted number -- of other products that remain on the market, all lots remaining in the two distribution centers, and the in-process products that remain at the firm's Little Falls, New Jersey, and Totowa, New Jersey, locations. The products were manufactured, tested and released by the same quality system.

Now, do you find praise in that --

Go ahead.

THE WITNESS: You asked something specific to digoxin.

MR. DEAN: He changed the question.

MR. MILLER: I did because I forgot the first one. You're going to get me to forget the second one if you don't give me an answer.

MR. DEAN: Why don't you try again.

BY MR. MILLER:

Q As the vice president of quality and compliance at Actavis for a large area but speaking to Totowa and all the products that manufacturing of was ceased, were all the products terminated because of violations of GMPs?

MR. DEAN: Objection.

Go ahead.

THE WITNESS: When we ceased manufacturing? You're referring to the cease of manufacturing?

BY MR. MILLER:

Q Yes.

A The products -- we discontinued manufacturing because Erin raised the concern regarding the fact that she couldn't -- she reviewed certain products and she had issues. And she extended that across the board and asked us to provide her with evidence to the contrary.

So in the absence of being able to present her now with evidence for every product, that it was -- that a review had been done and that it was good, we ceased manufacturing. And that's when we called PAREXEL in to do that review so that we could provide that to her.

Q And whether or not double-thick tablets were found in Digitek, production would have ceased on Digitek just the same?

MR. DEAN: Objection; misstates the prior testimony.

Go ahead.

MR. MILLER: I'm not stating any prior testimony.

BY MR. MILLER:

Q My question is: If double-thick tablets had never been discovered in any Digitek lot or batch, would you agree that production line would have stopped just the same?

A It would have been part of that group of products. Whatever we were manufacturing was stopped. So Digitek -- even if she never found an issue with Digitek, that's what you're asking?

Q Yes.

A If she never found any issue with Digitek, that would have been stopped with all the others.

Q No. I'm talking about that specific issue. There were several issues. I guess that specific issue of double-thick tablets, had that not been found, the production of Digitek still would have ceased?

A Yes, because we ceased everything. So it would have been included in the whole group.

Q And the whole group ceased because

of significant GMP violations?

A She found CGMP violations with respect to certain things that she had looked at and extended it across the board. And it was up to -- she was asking us to prove otherwise. So we had to stop in order to evaluate and provide that information.

Q And her findings came in the way of observations in the 483?

A Yes.

Q And it was those observations in the 483 and violations of the GMP written in that document that led to the cease of production of all products; you agree with that?

A Yes, even though we ceased before actually having the official 483.

Q Page 43 of 95, please.

And you agree that one group of production recalls were due to stability, but you agree that that was also -- included out-of-specification results; is that correct?

MR. DEAN: Can I have that question again? I'm sorry.

MR. MILLER: Well, yeah, I

A Correct.

Q If it was some other product that they make, even if they had said by way of example oxycodone hydrochloride tablets and that was the example, it wouldn't matter because the violation is a general violation that's outlined at the top; right? So it wouldn't have mattered to you --

A She's pointing out, yeah, what she observed to be a violation.

Q I understand. And if you take a look at Page 45 of 95, now, this issue, this out-of-specification issue goes to -- am I correct in using the term "blend uniformity"?

A In the last example?

Q Yes.

A Yes.

Q And blend uniformity is where you're testing to see if the amount of active pharmaceutical ingredient has dispersed evenly in the mixture; is that a good way to put it?

A That's a good way to put it.

Q And "out of specification" means that a sample that they took did not have the

proper amount of active pharmaceutical ingredient?

A It could mean that, but there are a lot of -- there's a lot of debate about the sampling technique playing a role in whether you get an accurate result.

Q But as a manufacturer of a product and vice president of quality, you do have limits set high and low of how much active pharmaceutical ingredient can be in a blend uniformity test?

A It has to meet the criteria for the finished dose.

Q Right. And in this example, it was Digitek that did not have the right amount of digoxin in the test sample; is that correct?

A If I can just look at this one more time.

Q Certainly.

A I don't know all the details here, but -- it's hard to do this with the redacted version. What was the question again?

Q Certainly. It discusses a Right-Top sample. You saw that?

A -- it's a valid result.
Q But ultimately you'd agree that the CGMP violation that the FDA inspector found to summarize all this was determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials?
MR. DEAN: Object to the form as to "found."
Go ahead.
THE WITNESS: Her concern here was that this issue didn't extend to looking at the manufacturing process. She's criticizing the fact that a manufacturing investigation wasn't conducted in this instance and that -- but it appears, in looking at the rest of this, that there were -- there was some type of investigation related to the laboratory and additional samples were tested.
BY MR. MILLER:
Q Would you --
A As I said, unless I read this whole

[redacted]

Q But as a result of the inspection, you agree that all products were recalled at Totowa?

A Eventually.

[redacted]

anything else going on in the inspection except that they were not happy with what they had seen so far.

And so when the Digitek one came along, they took a harsher approach in looking at it and most likely due to the nature of the product, but that's just my opinion.

BY MR. MILLER:

Q Did they also take a harder look because of the significant GMP issues that were going on in the laboratory?

A Her -- no, it had nothing to do with the laboratory.

Q I'm sorry. Strike that.

A This particular observation had absolutely nothing to do with the laboratory.

Q Let me rephrase the question.

You agree that there were significant GMP deficiencies found in the quality control system?

MR. DEAN: Objection. That's been asked and answered about ten times.

MR. MILLER: Well, I'm trying

about --

A Now ask me the question again.

Q I'll start the same way I started last time.

The other products, the other 64 or 65 products, they were subject to a quality control system that had significant deficiencies with GMPs; correct? Do you agree with that?

A That was the view that FDA took.

Q What's different about Digitek? Why is Digitek not lumped in with those other 65 products?

A Because of the time frame that you're talking about. Digitek was in April, and the 65 products was in July.

Q I'm talking about the findings of the 4 --

MR. DEAN: Let her finish.

THE WITNESS: In April, we had no intention of recalling the other 65 products. In April, it was our intention to do the review by PAREXEL of the remaining products and be able to defend

everything back. That's the story. I'm sorry. I get -- I spent ages and ages trying to defend it, and we brought it all back anyway. So I'm very passionate about this topic.

BY MR. MILLER:

Q It is your testimony today that up to April 24th of 2008, the only product that was being discussed to be recalled was Digitek?

A No. It was Digitek and several of the stability-related out-of-spec products. And there's documentation with dates and commitments. And I put everything in writing, so it should be here somewhere, the exhibits that are referred to.

MR. MILLER: That's all the questions I have.

MR. DEAN: I've got a few questions.

THE VIDEOGRAPHER: We should probably go off the record, and I'll give you a new clip.

MR. DEAN: Oh, please. That

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, PHYLLIS A. LAMBRIDIS, have the opportunity to read and sign the deposition transcript.

KIMBERLY A. OVERWISE
Certified Realtime Reporter
Notary Public
Dated: January 29, 2010

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

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ACKNOWLEDGMENT OF DEPONENT

I, PHYLLIS A. LAMBRIDIS, do hereby certify that I have read the foregoing pages, 1-396, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

PHYLLIS A. LAMBRIDIS DATE

Subscribed and sworn
to before me this
____ day of _____, 2009.

My commission expires:_____

_____
Notary Public